UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,716	01/16/2004	Raymond P. Warrell JR.	CELLTH 3.0-003 CONT CONT	8216

530 7590 11/16/2004

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
PRYOR, ALTON NATHANIEL	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,716	WARRELL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 9/1/04 have been fully considered but they are not persuasive. See arguments below.

I. Rejection of claims 1-22 under 35 USC 103(a) as being obvious over Zhang (US '011) or Chen (Blood, 1996, 88(3), pp. 105261) will be maintained for reason on record and reason as follows. Rejection of claims 1-22 over Yang will not be maintained. Applicant is correct in that Yang's invention is not to the treatment of myelobastic leukemia using ATO.

Applicant argues that Chen teaches a method of treating APL patients with 10 mg per day of ATO for 28-60 days. Applicant argues that Chen's treatment regimen is a flat dose amount rather than dosage according to body weight. Examiner argues that although Chen does not explicitly teach ATO dosing based on body weight it is obvious within the language of a "therapeutically effective dosage". See instant claim 1.

Applicant argues that Zhang teaches a method of treating APL and AML by administering 1-10 mg ATO to patient in need thereof. Applicant argues that the actual dose administered to the patient in Zhang is a 10 mg flat dose of ATO rather than ATO administration by body weight as instantly claimed. Applicant acknowledges that Zhang teaches that smaller dosages should be administered to children. However, Applicant points out that Zhang does not provide an example of administering less than 10 mg of ATO to children. Examiner argues that the fact that Zhang discloses a range of ATO (1-10mg) and the administration of smaller doses of ATO to children suggests that ATO can be administered according to a subject's body weight. Examiner argues that Zhang is not required to show treatment regimen using all points in his disclose dose range of 1-10 mg of ATO. The fact that Zhang teaches a range of 1-10 mg of ATO

suggests that dose amounts other than 10 mg can be administered to patients in need thereof. Although Zhang does not explicitly teach ATO dosing based on body weight, it is obvious within the language of a "therapeutically effective dosage". See instant claim 1.

Applicant provides Ellison's Declaration to show that administration of ATO was done according to Body Surface Area (BSA) rather than according to body weight. Examiner refers to arguments above to illustrate that the prior art does suggest the administration of ATO according to body weight rather than according the BSA and / or flat dose amount. However, note that Ellison's declaration in this application is irrelevant since claims are directed to a kit rather than to a method of administration.

II. Double Patenting Rejection of record will not be maintained. Applicant has filed terminal disclaimer to overcome rejection.

III. New Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6770304. Although the conflicting claims are not identical, they are not patentably distinct from each other because

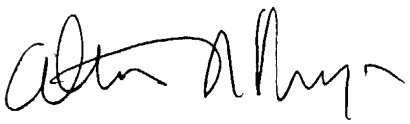
USPN '304 teaches a Markush group of cancers of which myeloblastic leukemia is specifically claimed. USPN '304 teaches that the dose must be a "therapeutically effective amount of ATO which is the same requirement for instant claim 1. The limitation in Applicant's claim 1 (based on the weight of the subject) is obvious within the language of "a therapeutically dose" of the patent claim.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alton Pryor
Primary Examiner
AU 1616